

North Carolina Central University Science & Intellectual Property Law Review

Volume 9 | Issue 1

Article 1

4-1-2016

A Myriad of Reasons: Incentives for Innovation in Genetic Research and Diagnostics Post-Myriad

Zachary King

Follow this and additional works at: <https://archives.law.nccu.edu/siplr>



Part of the [Genetic Structures Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

King, Zachary (2016) "A Myriad of Reasons: Incentives for Innovation in Genetic Research and Diagnostics Post-Myriad," *North Carolina Central University Science & Intellectual Property Law Review*: Vol. 9 : Iss. 1 , Article 1.

Available at: <https://archives.law.nccu.edu/siplr/vol9/iss1/1>

This Article is brought to you for free and open access by History and Scholarship Digital Archives. It has been accepted for inclusion in North Carolina Central University Science & Intellectual Property Law Review by an authorized editor of History and Scholarship Digital Archives. For more information, please contact jbeeker@nccu.edu.

A MYRIAD OF REASONS: INCENTIVES FOR INNOVATION IN GENETIC RESEARCH AND DIAGNOSTICS POST- *MYRIAD*

ZACHARY KLING*

INTRODUCTION

Imagine a world in which the very essence of your being is owned by various corporations and institutions. These groups profit off of ascertaining exactly what is contained within your genetic code. They exclude you and others from learning what your code says about you, unless you pay them for the information. In a manner, this is what has been happening in the field of genetic diagnostics for many years until the Supreme Court's decision in *Association for Molecular Pathology v. Myriad*.¹

On January 3, 2000, British artist Donna Rawlinson Maclean attempted to reserve her unique genetic code by submitting a patent application titled "Myself."² She filed her application, GB0000180.0, in the British Patent Office to protest the above-described scenario.³ Brian Caswell, an agent at the British Patent Office, seemed confused as to why someone would submit such a patent.⁴ On the topic of the patent application, Caswell said, "It is not really worth patenting something unless you make a lot of money from it."⁵

* J.D. Candidate at Indiana University Robert H. McKinney School of Law.

1. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

2. *Of Her Own Making*, N. Y. TIMES, (Mar. 12, 2000), <http://www.nytimes.com/2000/03/12/business/business-diary-of-her-own-making.html>, archived at <http://perma.cc/CQ6K-MXSV>.

3. *Id.*

4. *Woman Files Patent Application on Herself*, INST. FOR AGRIC. AND TRADE POL'Y, (Mar. 3, 2000), <http://iatp.org/news/biotech-activists-030300-woman-files-patent-application-on-herself>, archived at <http://perma.cc/M5K9-XKSJ>.

5. *Id.*

Undoubtedly, Ms. Maclean was not likely to realize robust profits from her patent, or any at all, but a lot of money had been made from products protected from competition by genetic patents at that time. For instance, in the year 2000, one product protected by a gene patent accounted for more than \$1.9 billion of one company's \$3.6 billion in total revenue.⁶

The commercialization and monopolization of humanity's shared genetic code disturbed more than just a British performance artist with a flair for the dramatic. Other parties concerned with the patenting of human genes included medical professionals, researchers in genetic epidemiology, and policy-makers to name a few.⁷

As the years went on, more and more of the human genome became patented.⁸ In 2009, the controversy came to a head when the American Civil Liberties Union (ACLU) filed a lawsuit in the Southern District of New York naming twenty plaintiffs that included the United States Patent Office, Myriad Genetics, and ten directors of the University of Utah Research Foundation as defendants.⁹

This case went all the way to the Supreme Court.¹⁰ In the summer of 2012, in a decisive, unanimous decision penned by Justice Thomas, the Court found for the plaintiffs on patents that claimed genomic DNA.¹¹ In this single decision, the Court invalidated the patents that laid the foundation for an entire industry.¹²

The decision was a hard-won victory for those concerned with the ability of private companies to own the rights to the human genetic

6. See Amy Tsao, *Amgen: Will Bigger Be Better?* BUSINESS WEEK ONLINE, Jan. 2, 2002,

http://www.businessweek.com/bwdaily/dnflash/jan2002/nf2002012_2995.htm.

(EpoGen, a product protected by a patent on the human erythropoietin gene, accounted for 1.9 billion dollars of Amgen's nearly 3.6 billion dollar revenues.).

7. Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 66 (2002).

8. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE (5746) 239-240 (October 14, 2005).

9. 28 U.S.C. § 1295; *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

10. See generally *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107 (2013).

11. *Id.* at 2119.

12. *Id.*

code, but is it possible that they were shortsighted and focused too narrowly on the seemingly unjust nature of “owning” a person’s genetic code? After all, the genes in question in *Myriad* were being used to identify whether a person may develop breast cancer, a laudable goal. Perhaps without the security of genetic patents, researchers would no longer be encouraged to find such gene-to-disease correlations. Perhaps that may be the case, but is there anything left to incentivize researchers? And, if there is, what exactly is left to incentivize these innovative genetic diagnostics companies?

This Note addresses the incentives remaining for innovation in the genetic diagnostics field after the Supreme Court’s decision in the *Myriad* case. Part I is an overview of patent law in the United States develops the reader’s understanding of what a patent is, what is generally patentable, and the steps necessary to secure a patent in the United States. Part II discusses genes, genetic diagnostics, and gene patents. Part III delves into the controversy surrounding gene patents, including a discussion of both proponent’s and opponent’s positions on the granting of gene patents.

Part IV contains a discussion of *Myriad* from the district court all the way up to the Supreme Court that lays out the legal rationale behind the invalidation of patents the genetic diagnostics community believed were invaluable to their field. Finally, Part V analyzes what remains post-*Myriad* to incentivize genetic researchers to look for gene sequence associations to diseases and to develop the diagnostics to test for these gene sequences. This final Part reveals that not all was lost due to the invalidation of key patents protecting the industry and that many means remain by which genetic researchers and diagnostics providers can maintain incentive and competitive advantage to continue their work.

I. PATENT LAW IN THE UNITED STATES

Patent law in the United States has its foundation in the Constitution.¹³ The “Intellectual Property” clause (the “IP clause”), or “patent and copyright clause,” confers upon the government of the United States the authority and obligation to provide protection to those who

13. See U.S. CONST. art. I, § 8, cl. 8.

advance the sciences or the useful arts.¹⁴ The IP clause can be found at Article 1, Section 8, Clause 8 of the United States Constitution and provides Congress with the power “[t]o promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries.”¹⁵ Inventors who have patents issued to them are referred to as “patentees.”¹⁶

To this end, Congress has enacted legislation to protect inventors and their advances to the “useful arts” by providing protection through what is known as a patent.¹⁷ According to the United States Patent and Trademark Office (the “USPTO”), the agency responsible for the issuance of patents and trademark registrations within the United States, a patent is:

a property right granted by the Government of the United States of America to an inventor ‘to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States’ for a limited time in exchange for public disclosure of the invention when the patent is granted.¹⁸

Thus, patent rights are a negative property right.¹⁹ Holding a patent alone does not allow a patentee to actually practice, make, or even use their invention.²⁰ The patent, as explained in the above quoted language, allows only the power to exclude others from making use of the patented invention.²¹ A prime example of this is in the pharmaceutical industry. Almost every pharmaceutical product has, at least at the beginning of its lifecycle, various patents that claim the chemical composition of the drug or the formulation of the drug

14.*Id.*

15.*Id.*

16.35 U.S.C. § 100(d) (2015).

17.*See generally* 35 U.S.C. §§ 101-103 (2015).

18.*Patents for Inventors*, USPTO (Jan. 26, 2015), <http://www.uspto.gov/inventors/patents.jsp>, *archived at* <http://perma.cc/7YYP-RKYP>.

19.*Id.*

20.*Id.*

21.*Id.*; *see also* 35 U.S.C. § 271 (concerning infringement of patents).

product made with that chemical composition.²² Yet, to reach the market and actually be able to sell their inventions, innovator pharmaceutical companies must jump through the regulatory hoops of the Food and Drug Administration (the “FDA”).²³

Patents in the United States are more fully governed by the Patent Act, which is codified at 35 U.S.C. §§ 1–376. To be granted a patent, Congress established that the claimed invention must be patentable subject matter as defined in 35 U.S.C. § 101. Patentable subject matter is defined as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”²⁴ This definition has been found to exclude from the realm of patentable subject matter inventions that claim laws of nature, products of nature, or abstract ideas.²⁵

Further requirements for patentability include novelty, non-obviousness, and utility.²⁶ Novelty generally requires that the claimed invention be one that is new and has not been claimed in a previous patent application in the United States or any other country.²⁷ Non-obviousness requires that the invention or modification to a prior invention not be obvious to a person who has ordinary skill in the science underlying the invention.²⁸ Utility requires that an invention have some use.²⁹ Thus, one cannot patent something that has no use or purpose capable of being exploited.³⁰

22.Katherine N. Addison, *The Impact of the Biosimilars Provision of the Heath Care Reform Bill on Innovation Investments*, 10 J. MARSHALL REV. INTELL. PROP. L. 553, 571 (2011).

23.21 U.S.C. § 355(a); *See also* Katherine N. Addison, *The Impact of the Biosimilars Provision of the Heath Care Reform Bill on Innovation Investments*, 10 J. MARSHALL REV. INTELL. PROP. L. 553, 571 (2011).

24.35 U.S.C. § 101 (2012).

25.*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

26.35 U.S.C. §§ 101-103 (2012).

27.35 U.S.C. § 102 (2012).

28.35 U.S.C. § 103 (2012).

29.*See* 35 U.S.C. § 101 (2012).

30.*Id.*

II. GENES: WHAT ARE THEY AND HOW CAN YOU PATENT THEM?

A. What is DNA?

When the ordinary, non-scientist thinks of a gene, he or she most likely understands that genetic information is carried in a person's DNA, and their individual genes are somehow responsible for making them who they are. It then follows from that understanding that a single gene is the section of DNA that provides for some physical characteristic or trait of an individual.³¹ At the most basic level, this is essentially correct. However, a little more depth on the topic of precisely what a gene is and how they have been claimed in patents will help lay the groundwork for the discussion at hand.

That simplistic take on what a gene is should generally be a satisfactory working definition for most people, but how do professional geneticists and other scientists define a gene? Those scientists cannot even decide what exactly the definition of a gene ought to be.³² As scientists learn more about biology, and genetics specifically, the definition of what a gene is and exactly what it does are in flux.³³

Deoxyribonucleic acid (DNA) is the source code for everything human bodies are programmed to do.³⁴ This includes the information that is eventually responsible for eye color, hair color, the growth of limbs, and the ability of nerves to transmit sensations to the brain.³⁵ DNA is structured in a twisted double helix, like a spiraling ladder.³⁶

31. *Black Bag* at BB4, OAK RIDGE NATIONAL LABORATORIES, available at http://www.ornl.gov/sci/techresources/Human_Genome/publicat/, archived at <http://perma.cc/29E8-FGQ6>

32. See Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 161 (2010) (“[D]ebates about what a ‘gene’ really is have raged within the biology community.”).

33. *Id.* at 160-61.

34. See generally National Institutes of Health, *A Brief Guide to Genomics*, NATIONAL

HUMAN GENOME RESEARCH INSTITUTE, <http://www.genome.gov/18016863>, archived at <http://perma.cc/H2GR-JAD7>.

35. OAK RIDGE NATIONAL LABORATORIES, *supra* note 31, at BB4

36. James D. Watson & Francis H. C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953) (unveiling the twisted-helix DNA structure that Watson and Crick discovered).

On each side of the ladder are strands of deoxyribose, which is a sugar, and some phosphate molecules.³⁷ Connecting the sides of the ladder is a nucleotide pair, referred to as a base pair.³⁸ Nucleotides consist of four different chemicals, each of which is referred to by a single letter: adenine (“A”), guanine (“G”), thymidine (“T”), and cytosine (“C”).³⁹ In these base pairs, an A is always paired with a T, while a G is always paired with a C.⁴⁰ Each strand of DNA, split down the middle of the ladder, can then be expressed as a sequence identified by letters corresponding to each nucleotide in the sequence.⁴¹ Found in this string of letters are certain three-letter nucleotide sequences that code for the production of an amino acid, the basic building blocks of proteins.⁴² These sequences are called “codons.”⁴³ Codons work together to provide for the synthesis of proteins.⁴⁴ These cooperating codons are called “exons.”⁴⁵ However, exons are only a tiny fraction of the human genome and are frequently not contiguous in the DNA sequence.^{46, 47} It turns out that most of the human genome is not responsible for the programming of anything.⁴⁸ These portions of DNA sequence that do not code for amino acid production are called “introns,” which comprise over ninety-eight percent of the human genome.⁴⁹

Human gene patents are written to claim the isolated strand of DNA that contains a group of exons found to code for some trait that

37. See NATIONAL HUMAN GENOME RESEARCH INSTITUTE, *supra* note 34.

38. Jonah D. Jackson, Note, *SOMETHING LIKE THE SUN: WHY EVEN “ISOLATED AND PURIFIED” GENES ARE PRODUCTS OF NATURE*, 89 TEX. L. REV. 1453, 1458 (2011).

39. NATIONAL HUMAN GENOME RESEARCH INSTITUTE, *supra* note 34.

40. Jackson, *SUPRA* NOTE 38, at 1458.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.*

46. Anthony J. F. Griffiths et. al., MODERN GENETIC ANALYSIS INTEGRATING GENES AND GENOMES, at 302 (2d ed. 2002).

47. Jackson, *SUPRA* NOTE 38, at 1458.

48. OAK RIDGE NATIONAL LABORATORIES, *supra* note 31, at BB5.

49. *Id.* (“Less than 2% of the genome codes for proteins.”).

may be commercially valuable.⁵⁰ These patents are filed as composition-of-matter patents claiming the actual, genomic DNA.⁵¹

The USPTO also granted patents claiming what is known as complementary DNA, or cDNA.⁵² Complementary DNA is a synthetically produced copy of DNA that contains only the active exons of a gene.⁵³ The process used to create cDNA is “well known in the field of genetics” and “[o]ne such method begins with a messenger RNA molecule, a naturally occurring ribonucleic strand that contains only exons, and uses [it] to create a new, synthetic DNA molecule.”⁵⁴

III. GENE PATENTS IN THE UNITED STATES

The history of gene patents in the United States starts in 1973.⁵⁵ In that year, the USPTO issued the first patent that included DNA as an element of the claimed material.⁵⁶ Later that same year, the USPTO issued a patent that claimed a gene as an element in the production of commercial hybrid maize.⁵⁷ In 1982, the USPTO granted the first patent application directed to human and animal genes.⁵⁸

The Supreme Court first addressed the validity of patents claiming the genetic material of living beings in *Diamond v. Chakrabarty*.⁵⁹ In that case, the USPTO denied a patent application claiming a bacterium that was created through the combined DNA of four other microbes.⁶⁰ The application was denied because, at the time of the application, it was thought that claims to living things were not pa-

50. See generally Jackson, *supra* note 38 (discussing the isolation and purification doctrine as it relates to the patenting of genes as compositions of matter).

51. *Id.* at 1453.

52. See generally *Myriad Genetics, Inc.*, 133 S.Ct. 2107.

53. *Id.* at 2112.

54. *Id.*

55. Torrance, *supra* note 32, at 176.

56. *Id.*

57. *Id.*

58. *Id.* at 176-77 (claiming a “[r]ecombinant DNA vector[s] comprising specified nucleotide sequences of codons for ‘human chorionic somatomammotropin’ and ‘the growth hormone of an animal species’ respectively.”).

59. See generally *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

60. *Id.*

tentable subject matter.⁶¹ In the opinion in *Chakrabarty*, Chief Justice Burger wrote to remind the USPTO that it and the courts “should not read into the patent laws limitations and conditions which the legislature has not expressed.”⁶² The Court determined that by its terms, the subject matter requirement of § 101 of the Patent Act was expansive in nature.⁶³ This determination was based on the terminology used to define patentable subject matter, which uses the generic terms “manufacture” and “composition of matter” that “plainly contemplate[] that the patent laws would be given wide scope.”⁶⁴ Taking that reading of the Patent Act even further, the Court announced that the scope of patentable subject matter “include[s] anything under the sun that is made by man.”⁶⁵

The key to that holding, and why the challenge to the particular patent in question was made, turned on whether the genetically modified bacterium engineered to eat oil claimed in the patent was a “product of nature.”⁶⁶ The Court made clear that the products and laws of nature are not patentable subject matter:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . “Such discoveries are manifestations of . . . nature, free to all men and reserved exclusively to none.”⁶⁷

However, the Court concluded that the bacterium in question was not a product of nature because the organism was only in existence due to the machinations of man, not nature.⁶⁸ Therefore, the patent application claiming the bacterium was acceptable under the

61.*Id.*; Ricki Lewis, *A Brief History of DNA Patents*, DNA SCIENCE BLOG (June 20, 2013), <http://blogs.plos.org/dnascience/2013/06/20/a-brief-history-of-dna-patents/>, archived at <http://perma.cc/JQN7-22P2>.

62.*Chakrabarty*, 447 U.S. at 308 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178 (1933)).

63.*Id.* at 308-09 (1980).

64.*Id.* at 308.

65.*Id.* at 309 (citations omitted).

66.*Id.* at 306.

67.*Id.* at 309 (citations omitted).

68.*Id.*

expansive reading of patentable subject matter announced by the Court.⁶⁹

After the *Chakrabarty* decision, the USPTO began granting many of the gene patent applications it received, eventually including patents claiming human genes.⁷⁰ By 2005, the USPTO had issued patents granting exclusive rights to some 4,382 of the 23,688 genes that comprise the human genome.⁷¹ That is nearly twenty percent of the human genome that was reserved exclusively to their respective patent holders.⁷² The decision of the United States Supreme Court in *Myriad* put an end to the issuance of patents claiming naturally occurring DNA.⁷³ However, it did leave intact the patents issued claiming cDNA and will allow future patent applications directed toward cDNA.⁷⁴

IV. THE CONTROVERSY OF GENE PATENTS

Beginning with the first gene patent issued, there has been a fiery debate about the propriety of gene patents.⁷⁵ Innovators have supported gene patents as a means to ensure that their research investment will be recouped.⁷⁶ Opponents claim that gene patents violate patent law, the Constitution, and are against public policy as they allow corporate interests to monopolize people's access to their own genetic information.⁷⁷ Part IV details the claims on both sides of the debate to frame it as a legal, business, and social issue.

69.*Id.*

70.Torrance, *supra* note 32, at 176.

71.Kyle Jensen & Fiona Murray, *supra* note 8, at 239-240.

72.Some quick math would reveal that the amount of the human genome that had a patent claiming it by 2005 was 18.5%.

73.*See generally Myriad Genetics, Inc.*, 133 S.Ct. 2107.

74.*See id.*

75.*See generally BRCA FAQs*, AMERICAN CIVIL LIBERTIES UNION, <https://www.aclu.org/free-speech/brca-faqs> (last visited Oct. 10, 2014), *archived at* <http://perma.cc/3FQ6-VZDF>.

76.*See infra* notes 118-138 and accompanying text.

77.*See infra* notes 78-117 and accompanying text.

A. Opposition to Gene Patents

1. Legal Arguments

The opposition to gene patents comes from many groups who have various legal and social concerns regarding the propriety of these patents.⁷⁸ The groups who oppose these patents include medical professionals, civil rights advocates, the American Association of Retired Persons (the “AARP”), and the Southern Baptist Convention, to name a few.⁷⁹

Legal arguments claiming that DNA in molecular form should not be patent eligible subject matter under 35 U.S.C. § 101 were the most pervasive arguments of many opponents made in public statements and in various *amicus* briefs filed in support of AMP and the plaintiffs.⁸⁰ The plaintiffs and their *amicus* made an argument under § 101 that isolated-gene patents should be considered a product of nature, and, as discussed above, should not be eligible for patent protection.⁸¹

Regarding the § 101 issue, the AARP in its *amicus* brief to the Federal Circuit argued that “DNA molecules and human genes are natural phenomena that when discovered are not the kind of ‘discovery’ that Section 101 was designed to protect.”⁸² In its federal circuit *amicus* brief, the AARP cited *American Wood-Paper Co. v.*

78. See AMERICAN CIVIL LIBERTIES UNION *supra* note 75.

79. See *Myriad Genetics, Inc.* 133 S. Ct. at 2107.. (Plaintiff is the Association of Molecular Pathology, a group of clinical and research pathologists); see also Brief of Amici Curiae American Medical Association, et al, in Support of Petitioners, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013) (No. 12-398), 2013 WL 390998; Brief for AARP as Amici Curiae Supporting Petitioners, Ass’n for Molecular Pathology v. United States Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585711. Brief for the Southern Baptist Convention as Amici Curiae Supporting Petitioners, Ass’n for Molecular Pathology v. United States Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585712; AMERICAN CIVIL LIBERTIES UNION, *supra* note 75.

80. See generally *Myriad Genetics, Inc.*, 133 S. Ct. 2107.

81. See generally *id.*

82. Brief for AARP as Amici Curiae Supporting Petitioners, Ass’n for Molecular Pathology v. United States Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585711, at *2.

Fiber Disintegrating Co., 90 U.S. 566 (1874), to analogize the isolation of DNA to that of “removing pulp from straw, wood, or other natural sources.”⁸³ In *American Wood-Paper Co.*, the Supreme Court held that “merely removing pulp from straw, wood, or other natural sources did not make it a patentable new composition of matter: ‘A process to obtain it [an extract] from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.’”⁸⁴ Thus, the thrust of the AARP’s § 101 argument is that “[s]imilarly, isolating a gene . . . from the human body does not then make the [gene] itself patentable.”⁸⁵

Additionally, the ACLU pointed to language in *Chakrabarty* that also suggested human genes never should have been allowed to be patented.⁸⁶ The ACLU considers that the passage from *Chakrabarty* quoted above necessarily implies that human genes should not have been patentable.⁸⁷ The argument goes much like the AARP’s § 101 argument: genes are analogous to a mineral or plant discovered in the wild and merely isolating them is not enough to make them patent eligible subject matter.⁸⁸

2. Social Policies

Many of the arguments opponents made against allowing human genes to be patented were made in regards to the social implications of gene patents.⁸⁹ These concerns include restricting access to second opinions, discouraging genetic testing due to cost, and the potential to impede further research into the connections between certain gene sequences and disease states.⁹⁰ Opponents have also

83.*Id.* at *3 (citing Wood Paper Patent, 90 U.S. 566 (1874)).

84.*Id.* (quoting Wood Paper Patent, 90 U.S. 566 (1874)).

85.*Id.*

86.AMERICAN CIVIL LIBERTIES UNION, *supra* note 75.

87.*See supra* note 67 and accompanying text; AMERICAN CIVIL LIBERTIES UNION, *supra* note 75.

88.AMERICAN CIVIL LIBERTIES UNION, *supra* note 75.

89.*See infra* notes 90-111 and accompanying text.

90.*See generally* AMERICAN CIVIL LIBERTIES UNION, *supra* note 75.

claimed a moral, ethical, or religious disapproval regarding the patenting of genes.⁹¹

a. Patient care

In its *amicus* brief to the Federal Circuit, the AARP succinctly summed up the primary concerns related to patient care. It “urg[ed] the Court to find the [BRCA patents] invalid . . . [because] patents such as [these] prohibit diagnosis and treatment based on second medical opinions and discourage full medical testing . . . [along with] also significantly elevat[ing] the cost of genetic testing.”⁹² These assertions by the AARP are indicative of the opinion of many opponents of gene patents.⁹³

As the AARP pointed out, patient care was often foremost among the social policy concerns of gene patent opponents.⁹⁴ Thanks to the exclusivity granted to patent holders, gene patent holders could restrict other companies from running diagnostics to analyze patients’ genetic makeup.⁹⁵ In effect, this leaves patients without any access to a second opinion as to the diagnosis made by the patent holder genetic diagnostics laboratory, unless that patent holder agrees to license the gene patent or allow other laboratories to test for the individual gene that may indicate whether a patient is more likely to develop some disease.⁹⁶ To illustrate this concern, opponents point to several cease and desist letters Myriad Genetics sent to university

91. See generally Audrey R. Chapman, *Religious Contributions to the Debate on the Patenting of Human Genes*, 10 U. ST. THOMAS L.J. 650 (2013).

92. Brief for AARP as Amici Curia Supporting Petitioners, *supra* note 82, at 2.

93. See generally Eric Hoffman, Why Gene Patents Are Bad for Patients and Science, THE AMERICAN INTEREST (Aug. 9, 2011), <http://www.the-american-interest.com/articles/2011/8/9/why-gene-patents-are-bad-for-patients-and-science/#sthash.MDvyTHBH.dpuf> [<http://perma.cc/FR5T-FMT6>].

94. Brief for AARP as Amici Curiae Supporting Petitioners, *supra* note 82, at 3-4.

95. Karuna Jaggar, *Ruling to Overturn Human Gene Patents is a Huge Win For Women’s Health*, GENEWATCH, <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pagelid=474>, archived at <http://perma.cc/6DFV-KCG3> (last visited Oct. 10, 2014).

96. *Id.*

researchers who were testing for the BRCA genes in their not-for-profit clinical laboratories.⁹⁷

Gene patents could have also prevented the development of better and less expensive testing for patented genes due to the threat of infringement litigation.⁹⁸ In a survey of genetic research labs, upward of fifty percent of those labs reported that the possibility of infringement actions concerning patented genes led them to discontinue research into some genes.⁹⁹

Gene patents may also have provided physicians with incentives to violate the doctor-patient relationship.¹⁰⁰ One illustration of this can be found in the story of a businessman from Washington.¹⁰¹ John Moore was diagnosed with hairy-cell leukemia.¹⁰² For treatment, he travelled from his home in Seattle, Washington to the UCLA Medical Center, where he was the patient of a top specialist in Oncology.¹⁰³ His doctor ordered the removal of Moore's spleen and various other treatments.¹⁰⁴

After treatment and surgery, Moore continued to travel to and from Los Angeles for the next seven years for continued testing.¹⁰⁵ Moore thought he was being monitored for potential relapse and reappearance of his leukemia.¹⁰⁶ What actually was happening bordered on the? His physician was filing patents that claimed unique compounds in Moore's blood, a patent that claimed one isolated gene of Moore's, and was also entering contracts to develop a cell line using Moore's tissue.¹⁰⁷ One contract with a pharmaceutical

97.E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED., S39, S39 – S70 (2010).

98.Hoffman,*supra* note 93.

99.Mildred K. Cho *et al*, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 7 (February 2003).

100.*See infra* notes 101-11 and accompanying text.

101.*See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 480-81 (Cal. 1990).

102.*Id.*

103.*Id.*

104.*Id.*

105.*Id.*

106.*Id.*

107.*Id.* at 481-482.

company who wished to develop the cell line (named the Mo-cell line, after John Moore) was purportedly worth \$15 million dollars.¹⁰⁸

Moore said about the incident, “What the doctors had done was to claim that my humanity, my genetic essence, was their invention and their property. They view me as a mine from which to extract biological material. I was harvested.”¹⁰⁹ As a result of this mistreatment, Moore filed a suit that was dismissed primarily for its unusual nature, but Moore’s case was eventually heard and the California Court of Appeals ruled in his favor.¹¹⁰ However, the California Supreme Court eventually found that he had no property right in the patents and products derived from him, but only that he had meritorious claims as to the breach of the researcher’s fiduciary duty to Moore and a failure of informed consent.¹¹¹

b. Religious objections to gene patents

Various religious figures and organizations have also been vocal opponents of gene patents.¹¹² Their concerns with gene patents are not a unitary, monolithic voice, but have provided some viewpoints into the debate beyond the concerns for patients and the technical, scientific, and legal arguments against gene patents.¹¹³

Religious groups have raised concerns that the patenting of life forms and their genetic code “implies that human beings rather than God are the inventors of these forms of life.”¹¹⁴ This sentiment echoes the scientific argument against gene patents that the discoverers of valuable gene sequences are not actually inventing anything and, accordingly, should not be granted patent protection.¹¹⁵ A large group of faith-based organizations, which included Protestant, Catholic, Orthodox, Jewish, Muslim, Buddhist, and Hindu

108.*Id.* at 482

109. John Vidal & John Carvel, *Lambs to the Gene Market*, THE GUARDIAN (London), Nov. 12, 1994, at 1 (quoting John Moore saying he was “essence-raped”).

110. *Moore*, 793 P.2d at 502

111. *Id.* at 497.

112. *See generally* Audrey Chapman, *supra* note 91.

113. *See generally id.*

114. *Id.* at 668.

115. Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 ACAD. MED., 1381, 1384.

denominations, joined together to form the Joint Appeal Against Human and Animal Patenting.¹¹⁶ They released the following joint statement:

We, the undersigned religious leaders, oppose the patenting of human and animal life forms. We are disturbed by the U.S. Patent Office's recent decision to patent human body parts and several genetically engineered animals. We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions.¹¹⁷

B. Proponents of Gene Patents

1. Legal Arguments

Proponents of gene patents alleged that, as patented, genes were not products of nature.¹¹⁸ This argument flows from the fact that composition of matter patents had been granted to substances that were isolated and purified from their source.¹¹⁹ Judge Learned Hand, in *Parke-Davis & Co. v. H.K. Mulford Co.*, explained the isolation and purification doctrine.¹²⁰ In that case, the patentee had claimed ownership over the chemical compound adrenaline.¹²¹ By claiming the chemical, the patentee was able to exert exclusivity over a chemical compound that occurs naturally in all people¹²²

He was able to do so because, as Judge Hand found, the claimed substance was different in chemical compound, due to its separation from the gland producing it, and because of its therapeutic effect, which results from the concentration of the chemical and the removal

116.Chapman, *supra* note 91 at 662-63.

117.*Joint Appeal Against Human and Animal Patenting*, text of the press conference announcement made available by the General Board of Church and Society of the United Methodist Church, Washington, D.C. (May 17, 1995).

118.Kevin Noonan, *Why Genes Must Remain Eligible For Patenting*, GENEWATCH <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=304&archive=yes>, archived at <http://perma.cc/7C3S-PKED>.

119.*See generally* *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911); *see also* *Merck & Co v. Olin Mathieson Chemical Corp*, 253 F.2d 156 (4th Cir. 1958).

120.*See Parke-Davis & Co.* at 103.

121.*Id.* at 95.

122.*Id.*

of other substances.¹²³ Judge Hand described the differences made by isolating and purifying adrenaline as a difference “not in degree, but in kind.”¹²⁴ Thus, the isolation and purification doctrine of chemical compound patents allows for the patenting of some naturally occurring substances after all.¹²⁵

Judge Hand’s analysis bolsters the argument of proponents of gene patents by the fact that most genetic sequence contain primarily “junk DNA,” as detailed in Part II, and necessarily require isolation of the active exon to be useful in a laboratory setting.¹²⁶ Furthermore, to be useful by diagnostics companies, gene sequences are “purified” by removing the “junk” and creating cDNA.¹²⁷ However, the claim that cDNA is the more useful version of the gene sequence seems to ignore the fact that innovator labs largely held patents that claimed the naturally occurring genomic DNA that are the source for cDNA.¹²⁸

There is also the fact that to disallow the patenting of genes would upset thirty years of patent policy in the United States.¹²⁹ The potential for economic chaos for the industry in the absence of gene patents was central to the argument.¹³⁰ Proponents of gene patents also pointed to the potential that, if human gene patents were invalid, then it may be that any number of antibiotics, petroleum, and animal products are ineligible for patent protection.¹³¹

123.*Id.* at 104.

124.*Id.* at 103.

125.*See generally id.* at 95. ;*see also Merck & Co*, 253 F.2d 156.

126.*See OAK RIDGE NATIONAL LABORATORIES*, *supra* note 31, at BB5

127.*See supra* notes 47 - 49 and accompanying text.

128.Andrew Pollack, *After Patent Ruling, Availability of Gene Tests could Broad-*
en, NEW YORK TIMES, June 13, 2013,

[http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-](http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?pagewanted=all&_r=0)
[of-genetic-tests-could-broaden.html?pagewanted=all&_r=0](http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?pagewanted=all&_r=0), *archived at*

<http://perma.cc/RL53-MQY4>.

129.*Ass’n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181, 220 (S.D.N.Y. 2010).

130.Noonan, *supra* note 118.

131.*Id.*

2. *Research Incentive*

The proponents of gene patents also refute the idea that gene patents create a monopolization of genetic information by inhibiting researchers other than the patent holder from conducting research.¹³² Kevin Noonan, a partner at McDonnell Boehnen Hulbert & Berghoff LLP, claims that the opposite may in fact be the case.¹³³ He points to the increase in the number of basic research reports on the genes in question in *Myriad* (BRCA1 and BRCA2) since the patents claiming the genes were issued.¹³⁴ As well, Noonan cites to multiple studies conducted in the early 2000's in the United States, Australia, Japan, and Germany that indicate gene patents rarely affect the research of academic scientists.¹³⁵

Noonan goes on to claim that the patent incentive has actually encouraged private research companies to accelerate their research into genetics.¹³⁶ The result of such acceleration may very well be an increase in the rate of discovery of the genetic markers that indicate an individual's potential to develop certain diseases.¹³⁷ He and other proponents of gene patents argue that when research is competitive then patients win in the end, because knowledge of their genetic information and the possibility of a more quickly available diagnostic or treatment results in better outcomes for them.¹³⁸

V. *MYRIAD: FROM NEW YORK TO D.C.*

The primary legal issue in dispute in the string of *Myriad* decisions was whether isolated genomic and complementary DNA sequences were patentable subject matter under § 101 of the United States Patent Act.¹³⁹ There were also several method claims involved in the lower court proceedings, which are not relevant to the discussion of

132.*Id.*

133.*Id.*

134.*Id.*

135.*Id.*

136 *Id.*

137.*Id.*

138.*Id.*

139.*See Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

the gene patents, as those patents concerned various methods by which Myriad was determining whether a potential therapeutic agent was effective in treating cancer.¹⁴⁰ Those method patents will be discussed in Part VI.

The case that eventually reached the Supreme Court began in federal district court in the Southern District of New York.¹⁴¹ The district court decided in favor of the plaintiff and issued an opinion invalidating Myriad's patents as subject matter unpatentable under § 101 of the Patent Act.¹⁴² Myriad appealed to the United States Court of Appeals for the Federal Circuit (the "Federal Circuit"), which reversed the lower court decision and held that Myriad's patents on the BRCA1 and BRCA2 gene were valid as to both genomic and complementary DNA.¹⁴³ Upon a writ of certiorari, the Supreme Court of the United States heard the case. In a unanimous opinion penned by Justice Thomas, the Court reversed the Federal Circuit in part and affirmed in part.

A. Southern District of New York

"The inquiry into an invention's patent eligibility is a fundamental one, and as such, 'the obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious.'"¹⁴⁴ This is merely a statement of the § 101 standard that patent eligibility is the threshold

140.*See id.*

141.*See id.*

142.*See id.*

143.*Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1358 (Fed. Cir. 2011); see also *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 689 F.3d 1303, 1337 (Fed. Cir. 2012) (affirmed court's decision to exercise declaratory judgment jurisdiction over this case, reversed the district court's grant of summary judgment with regard to Myriad's composition claims to isolated DNAs and affirmed the district court's grant of summary judgment with regard to Myriad's method claims directed to comparing or analyzing gene sequences, and reversed the district court's grant of summary judgment with regard to Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates of novel, man-made transformed cells).

144.*Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 219 (quoting *Parker v. Flook*, 437 U.S. 584, 593 (1978)).

question regarding the validity of a patent and must be answered before continuing on to other legal matters regarding the patent in question.¹⁴⁵ The District Court determined that the question regarding Myriad's BRCA gene patents was "whether the claimed compositions and methods constitute statutory subject matter or fall within the judicially created products of nature exception to patentable subject matter."¹⁴⁶

First, the court dismissed Myriad's initial defenses to the claim of ineligibility.¹⁴⁷ Myriad's first argument was that the court should not look to invalidate their gene patents on the grounds that the "carefully considered policy of the USPTO" . . . is 'entitled to great respect from the courts'" based on the presumption of validity of patents and the USPTO's consideration of the eligibility of gene patents.¹⁴⁸ This argument did not sway the court and it pointed to a Federal Circuit decision in saying that "[that court] has previously held that it owes no deference to USPTO legal determinations" and that "[the] court reviews statutory interpretation . . . without deference."¹⁴⁹

The court's analysis provided that Myriad's gene patents, as claimed, had no "markedly different characteristics" from a product of nature, despite Myriad's assertion that the isolation of the DNA molecules should render them patentable.¹⁵⁰ Focusing on the nature of DNA, the court determined that regardless of whether the DNA is native or isolated its primary function is to carry genetic information.¹⁵¹ Due to this functional concern, the Court decided isolated DNA does not have the requisite "different characteristics"

145. *See In re Bilski*, 545 F.3d 943, 950 (Fed. Cir. 2008) (en banc) ("Whether a claim is drawn to patent-eligible subject matter under § 101 is a threshold inquiry, and any claim of an application failing the requirements of § 101 must be rejected even if it meets all of the other legal requirements of patentability.").

146. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 220.

147. *Id.*

148. *Id.*

149. *Id.* at 221 (quoting *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004)).

150. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 227-228.

151. *Id.* at 227-229.

to allow patentability.¹⁵² Myriad's cDNA claims were also found invalid due to the court's determination that, despite containing only exons, cDNA is not "markedly different" from native DNA.¹⁵³

Myriad also asserted that the invalidation of their patents would comprise an unconstitutional taking, which the court called "novel," but "unpersuasive."¹⁵⁴ This was also the Court's analysis concerning Myriad's proposition that invalidating the patents would be in violation of the treaty obligations of the United States as embodied in the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").¹⁵⁵

B. The Federal Circuit: Round One

On appeal, the Federal Circuit affirmed the District Court in part and reversed the District Court in part.¹⁵⁶ The Federal Circuit affirmed the lower court's decisions regarding the methods patents, and reversed the decisions on the composition patents, which it found were directed to patent eligible subject matter as to both the native DNA and cDNA claims.¹⁵⁷ In finding that the composition of matter patents was valid, the court relied on the totality of the differences between native DNA and isolated DNA, rather than the more strict functionally informational approach the District Court used.¹⁵⁸

However, the Federal Circuit had the chance to hear the case again when the Supreme Court granted certiorari and remanded the case back to the court to review its decision in light of the Supreme

152.*Id.* at 232 ("Because the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. § 101.").

153.*Id.* at 230.

154.*Id.* 221-222 ("Myriad's novel takings argument runs counter to a long history of invalidation patent claims by the courts and is unsupported by legal precedent.").

155.*Id.* ("Articles 8.1 and 27.3 of TRIPS permit governments to incorporate public health concerns into their intellectual property laws and to exclude from patentability diagnostic, therapeutic, or surgical methods as well as particular inventions on the grounds of public interest.").

156.*Ass'n for Molecular Pathology*, 653 F.3d at 1358.

157.*Id.*

158.*Id.* at 1350-1354 ("[I]t is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit.").

Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹⁵⁹

C. The Federal Circuit: Round Two

On remand, the Federal Circuit maintained its position regarding all the claims in question.¹⁶⁰ However, in this decision the court made a definitive statement on the patent eligibility of cDNA.¹⁶¹ The court held that "the claimed cDNAs are especially distinctive, lacking the non-coding introns present in naturally occurring chromosomal DNA. They are even more the result of human intervention into nature and are hence patent-eligible subject matter."¹⁶²

D. The Supreme Court

In June 2013, the Supreme Court delivered an opinion that invalidated Myriad's gene patents and all other gene patents claiming native or genomic DNA, but maintained the validity of cDNA patents.¹⁶³

The Court sided with the District Court in determining that the native DNA patents were invalid due to their functionally informational value as demonstrated by the claims in the patents "focus on the genetic information encoded in the [genes]."¹⁶⁴ On cDNA, the Court clarified that cDNA patents remain valid as patentable subject matter because of the fact that human intervention is required to make the molecule.¹⁶⁵

The Court specifically addressed issues that were not implicated in its decision, which reveal some means by which innovator research

159. *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 132 S.Ct. 1794 (Memo) (2012); see *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012) (concerning the validity of certain methods patents).

160. *Ass'n for Molecular Pathology*, 689 F.3d at 1337.

161. *Id.* at 1329.

162. *Id.*

163. *Myriad Genetics, Inc.*, 133 S.Ct. at 2119 ("We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.").

164. *Id.* at 2118.

165. *Id.* at 2119.

and diagnostics labs may still have some patent claims to their discoveries.¹⁶⁶ Justice Thomas specifically noted that certain types of method claims might still be patentable.¹⁶⁷ Additionally, patents that involve “new applications of knowledge about . . . genes” are to remain patentable subject matter.¹⁶⁸ Lastly, there is the possibility that DNA in which the nucleotide order has been altered in some way may be patent eligible subject matter.¹⁶⁹

VI. WHAT’S LEFT: INCENTIVES FOR INNOVATION AND COMPETITION POST-MYRIAD

As has been detailed above, there are various grounds on which people and organizations opposed the patenting of human genes.¹⁷⁰ Supporters generally relied upon not upsetting the status quo and the argument that without gene patents there would remain little incentive for crucial genetic research.¹⁷¹ There are no legitimate parties arguing that research into the human genetic code and discovering the connection between genetics, diseases, and potential therapies is not a desirable course of action, but why should research labs and diagnostics companies continue to fund such ventures without the security afforded by gene patents? This Part of the Note outlines several means by which innovators may still be incentivized, including federal funding, other types of patents and patent protection in other markets. Additionally, this Note suggests the adoption of a proposed regulatory change that would have genetic diagnostics be regulated by the FDA and would afford some exclusivity to innovator labs under current regulatory exclusivity regimes.

166.*Id.*

167.*Id.*

168.*Id.*

169.*Id.* (“Scientific alteration of the genetic code presents a different inquiry and we express no opinion about the application of § 101 to such endeavors.”).

170.*See supra*, Part III.

171.*See supra* Part III.

A. Remaining Patent Protection

1. *cDNA Patents*

The holding in the Supreme Court's decision in *Myriad* leaving intact the viability of cDNA patents is key to the remaining incentive scheme for genetic researchers.¹⁷² Complementary DNA is generally viewed as the more commercially viable form of DNA.¹⁷³ This is because cDNA is the more easily manipulated form of DNA that is used to engineer plant, animal, and bacterial cells.¹⁷⁴ In addition, cDNA is the form of DNA used in most of the commercially available diagnostics due to the ability to synthesize more of, and thus amplify, the specific gene at which the diagnostic is targeted.¹⁷⁵

However, a significant problem with continuing to rely on cDNA patents for protection in the genetics field was not addressed by the Supreme Court in *Myriad*. Due to the advanced state of genetics technology and the widespread understanding of the process by which cDNA is synthesized, cDNA patents may very well be successfully challenged under § 103 for being obvious to a person skilled in the art.¹⁷⁶

2. *Methods Patents*

Some types of patents are likely to remain viable in the genetics field for quite some time, and were specifically singled out by the Supreme Court as potential sources of patent protection for genetic researchers.¹⁷⁷ Justice Thomas explained that “[h]ad *Myriad* created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.”¹⁷⁸ Based on this guidance from the Court, innovator diagnostics companies may be secure in the knowledge that if they do

172. *Myriad Genetics, Inc.*, 133 S.Ct. at 2119.

173. Pollack, *supra* note 128.

174. *Id.*

175. Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1415 (2013).

176. *Id.* at 1444; The obviousness problem with continuing to allow cDNA patents cannot be understated.

177. *Myriad Genetics, Inc.*, 133 S.Ct. at 2119.

178. *Id.*

devise some novel method of gene manipulation, they will be able to secure a patent for the innovation, so long as they can demonstrate that the claimed innovation meets the necessary requirements of patentability.

Furthermore, Myriad itself won a challenge to one of its method patents in the litigation leading up to the Supreme Court's decision.¹⁷⁹ The method patent that was unsuccessfully challenged concerned a method by which Myriad was determining the efficacy of certain potential cancer treatments.¹⁸⁰ The claimed innovation was challenged on the basis that it was simply applying a law of nature that cancer cells do not grow as well in the presence of an oncological therapy.¹⁸¹ This challenge seemed to be a good argument against the claimed method under the decision made by the Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*. In that case, the Court "invalidated claims directed to the relationship between concentrations of certain metabolites in the blood and the likelihood that a particular dosage of a thiopurine drug will be optimum."¹⁸² The Court held that "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"¹⁸³

Using the *Mayo* standard, the Federal Circuit decided that Myriad had supplied a sufficiently innovative step to avoid the natural law problem.¹⁸⁴ The reasoning of the court was that once a "composition of matter is [determined to be] patent eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature."¹⁸⁵

179.*Ass'n for Molecular Pathology*, 689 F.3d at 1309.

180.*Id.* at 1310.

181.*Id.* .

182.*Id.* at 1336 (quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct 1289, 1294 (2012)).

183.*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct 1289, 1290 (2012).

184.*Ass'n for Molecular Pathology*, 689 F.3d at 1335-1336.

185.*Id.* at 1336 ("The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible. The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth

However, despite its success on the aforementioned method claim, Myriad has more recently been the victim of some method patent invalidations at the hand of the Federal Circuit.¹⁸⁶ In *In re BRCA1*, the Federal Circuit invalidated a method claim for comparing a person's BRCA sequence with wild-type BRCA sequences to identify differences that may indicate an increased risk of breast cancer.¹⁸⁷ Additionally, the court invalidated another method claim for some diagnostic methods used to identify mutations in BRCA sequences, because the claimed steps and diagnostic methods did not contain any new process, design, or use of diagnostic tests or instruments.¹⁸⁸

As can be seen in recent court decisions, there are certainly more hurdles to successfully claiming a method in a patent.¹⁸⁹ However, the option is still available to genetic researchers and diagnostic innovators if they can clear those hurdles.

3. Gene Patent Protection Abroad

Despite no longer being able to patent naturally occurring genes in the United States, innovator researchers and diagnostic companies still have the option to apply for patent protection for discovered genes in countries that allow for the patenting of such genes.¹⁹⁰ Naturally occurring gene patents are still viable in at least three of the largest healthcare markets in the world: the European Union, Japan,

rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent eligible subject matter.”).

186. In the time between the *Mayo* and *Myriad* decisions and this case, the Supreme Court decided *Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014), which reinforced a two-step test to determine patent eligibility for claims containing abstract ideas; see *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 756 (2014) (citing *Alice* to establish that the two-step test requires identifying whether the claim contains an abstract idea and then determining whether there are other items in the claim that may render it patent eligible despite containing an abstract idea).

187. *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 756 (2014).

188. *Id.* at 766.

189. See *supra* notes 177-188 and accompanying text.

190. See *infra* notes 191-204 and accompanying text.

and Australia.¹⁹¹ There are also other countries in which gene patents remain valid, but this Note only addresses the possibility of securing gene patents in these three countries.¹⁹²

The European Patent Office (“EPO”), acting under the jurisdiction of the European Patent Organization, allows the patenting of genes following the guidelines of European Union directive 98/44/EC (the “Biotech Directive”).¹⁹³ The Biotech Directive provides that “biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”¹⁹⁴ However, the EPO will not grant patents directed to genes identified without an identified function.¹⁹⁵ Along with an identifiable function, the gene must also have a disclosed “industrial application” listed in the patent application.¹⁹⁶ “Industrial application” has had various interpretations applied to it, but a recent decision by the EPO determined that only a “concrete benefit” is required.¹⁹⁷ For example, a gene shown to be usable in the cure or diagnosis of a disease would be likely considered to have an immediate benefit to industry even though it may be profitable for any use.¹⁹⁸ A gene that shows promise that future research will lead to such a practical application will be insufficient to gain patentability.¹⁹⁹ This includes

191. See *Infra* notes 192-204 and accompanying text.

192. See generally *Executive Summary: Genetics, genomics, and the patenting of DNA*, WORLD HEALTH ORGANIZATION, available at <http://www.who.int/genomics/publications/background/en/>, archived at <http://perma.cc/4342-8HG3> (discussing the patenting of genes around the world and noting that genes can be patented in India, China, and potentially Brazil).

193. Andrew Sharples, *Gene Patents in Europe Relatively Stable Despite Uncertainty in the U.S.*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Mar. 23, 2011), <http://www.genengnews.com/insight-and-intelligenceand153/gene-patents-in-europe-relatively-stable-despite-uncertainty-in-the-u-s/77899385/>, archived at <http://perma.cc/PP7W-HH9N>.

194. Council Directive 98/44, art. 3, 1998 O.J. (L 213) 13, 18.

195. *Id.* at 15.

196. *Id.* at 18.

197. Sharples, *supra* note 193.

198. Naomi Hawkins, *Human Gene Patents and Genetic Testing in Europe: A Reappraisal*, 7:3 SCRIPTed 453, 461 (2010), <http://www.law.ed.ac.uk/ahrc/scripted/vol7-3/hawkins.asp>.

199. *Id.*

any claims that are speculative as to possible future uses.²⁰⁰ Under these guidelines, many of the genes that researchers and diagnostic companies would have patented in the United States should remain patentable in the European Union.

In 2009, the Japanese Patent Office (the “JPO”) included as patentable subject matter methods by which information can be gathered from the human body.²⁰¹ This guideline will clearly apply to the patenting of genetic material that may indicate possible disease states in a person.²⁰² However, the claim to the gene or DNA sequence must be carefully drawn to avoid including any step that involves judgment, diagnosis, or treatment of a person’s physical state, because the claim will then fail under the JPO’s rules excluding claims to “medical activity.”²⁰³

Finally, in Australia, courts that have had the opportunity to hear challenges to gene patents have simply dismissed the cases, and the higher courts have denied rehearing of the cases.²⁰⁴ As such, gene patents are still viable in Australia.

B. Academic Pursuits and Federal Funding

Regardless of patent protection, academic research facilities have long been a bastion of scientific advancements. As evidence of this, much of modern knowledge has been developed without any incentive beyond the accumulation of raw knowledge about the world, how it works, and ways in which humans can manipulate the natural order in productive ways.

In light of the fruitfulness of academic research, the federal government provides large amounts of funding for research into various fields of study, including various forms of genetic

200.*Id.*

201.Kenji Sugimaura & Rebecca Chen, *IPS Cell Technology Spurs Biological Patenting in Japan*, World Intellectual Property Review Annual 2013, at 66, 67 (2013), http://sugi.pat.co.jp/wp-content/uploads/2013/05/WIPR-2013-Annual_Page_1.pdf, [<http://perma.cc/BXJ5-5ZXV>].

202.*Id.*

203.*Id.*

204.Heidi Ledford, *Australian Gene-Patent Case Dismissed*, NATURE NEWS BLOG (SEP. 5, 2014, 18:46 BST), <http://blogs.nature.com/news/2014/09/australian-gene-patent-case-dismissed.html>, archived <http://perma.cc/F5TQ-J3Y4>.

research.²⁰⁵ In 2013, the National Institutes of Health reported that federal funding for genetics research, including categories such as “Gene Therapy,” “Gene Therapy Clinical Trials,” “Genetic Testing,” and a broad “Genetics” category, exceeded eight billion dollars.²⁰⁶

Genetic diagnostic companies may decide that, without adequate patent protection, that their business model may be better suited to simply developing the actual diagnostics used to commercialize the findings of academic researchers. This model would allow these companies to funnel their former research costs into the development of better diagnostics, which may lead to more commercial success because they can focus on supplying the best product rather than racing to find the next BRCA-type “goldmine.”

C. Regulatory Schemes

The FDA has the authority to regulate genetic tests, but does not currently do so except for genetic test kits.²⁰⁷ Test kits are diagnostics marketed as a commercial test sold directly to consumers or labs other than the lab that developed the test.²⁰⁸ On the other hand, laboratory developed tests (“LDTs”) are diagnostics developed and performed by only the single innovator lab to which all specimen samples, regardless of collection site, are sent for testing.²⁰⁹ The FDA does not currently regulate the validation or performance of LDTs.²¹⁰ However, the FDA has provided Congress with draft guidelines on the regulation of LDTs.²¹¹ As no decisions have been

205. *See generally Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC)*, NATIONAL INSTITUTES OF HEALTH (Feb. 5, 2015), http://report.nih.gov/categorical_spending.aspx, archived at <http://perma.cc/Z47V-BNBK> (describing the amount of money funneled into various areas of research).

206. *Id.*

207. *Regulation of Genetic Tests*, NATIONAL INSTITUTES OF HEALTH (Apr. 17, 2015), <http://www.genome.gov/10002335>, archived at <http://perma.cc/EB7J-MWPS>.

208. *Id.*

209. *Id.*

210. *Id.*; *See also Dolin, supra* note 175, at 1456-57 (showing that validation means the determination that a diagnostic test performs adequately the function for which it was designed to be used).

211. *See generally Laboratory Developed Tests*, FOOD AND DRUG ADMINISTRATION,

made in regards to the full implementation of those guidelines, this Note does not address the contents of those proposed guidelines. However, this Note does propose that the FDA should extend their current regulatory exclusivity scheme to cover LDTs and test kits and provide an exclusivity-based incentive for genetic research. This Note has identified one promising scheme proposed by Dr. Gregory Dolin.

Gregory Dolin, M.D., proposes that an expansion in the law that controls biologic drug products would help incentivize research into genetic diagnostics even in the absence of patent claims.²¹² He proposes that the non-patent market exclusivity regime that is currently in effect for biologic drug products could easily be extended to include genetic diagnostics classified as either LDTs or test kits.²¹³ This kind of market exclusivity would not be a barrier to research into or the development of new treatments or diagnostics that use the same gene sequences because his proposed scheme would only provide exclusivity to the marketer of tests intended to treat, cure, or diagnose a targeted disease.²¹⁴ Therefore, other researchers may freely use the identified genes in developing their own diagnostics or treatments for the same or other disease associated with that specific genetic sequence.²¹⁵ The application of the regulatory exclusivity regime will determine when the innovator will lose exclusivity, but FDA market exclusivity, which is variable in length, is generally far shorter than the twenty years of control granted by a patent.²¹⁶

D. Trade Secret

If the FDA declines to create or extend to LDTs some form of regulatory exclusivity, diagnostics companies still have the option to retain their test results as a form of trade secret. A trade secret is “[a] formula, process, device, or *other business information* that is kept

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm407296.htm>, archived at <http://perma.cc/47YG-JGJP>.

212.Dolin, *supra* note 175, at 1406.

213.*Id.* at 1399-1400.

214.*Id.* at 1459.

215.*Id.*

216.*Id.* at 1460.

confidential to maintain an advantage over competitors.”²¹⁷ However, the Uniform Trade Secrets Act (UTSA) provides that to be protectable the information must not be “generally known or ascertainable,” which makes it unlikely that a diagnostics company would be able to bring a state law claim under the UTSA.²¹⁸ That is why this Note describes this method of maintaining competitive advantage as a *form* of trade secret.

As a diagnostic laboratory conducts more tests, the lab will invariably accrue more knowledge about the amount and type of existing polymorphs of the gene that is the focus of the diagnostic.²¹⁹ Knowledge of the resulting disease rates correlated with certain polymorphs will allow that lab to more accurately establish the potential for a specific client to develop the disease associated with abnormalities within that gene.²²⁰ As noted above, the FDA does not currently regulate LDTs and, as such, the provider of a LDT may currently maintain its database of knowledge concerning polymorphs and subsequent correlation to development of disease a secret from regulators as well.²²¹ The idea behind maintaining this database of knowledge as secret is that having a more powerful diagnostic, in terms of predictive capability, that can more accurately describe a patient’s possibility of disease should increase the competitiveness of that diagnostic in the marketplace.²²² Patients and their doctors should want to know as much as possible about the patient’s specific

217.Trade Secret, BLACK’S LAW DICTIONARY (9th ed. 2009) (emphasis added).

218.Uniform Trade Secrets Act § 1.4(i) (defining trade secret as “information . . . not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use.”).

219.Courtenay C. Brinckerhoff, *Myriad’s Trade Secret Trump Card: The Myriad Database of Genetic Variants*, FOLEY & LARDNER, LLP, available at <http://www.pharmapatentsblog.com/2013/07/18/the-myriad-database-of-genetic-variants/>, archived at <http://perma.cc/LS6S-X2WG>.

220.*Id.*

221. *Regulation of Genetic Tests*, NATIONAL INSTITUTES OF HEALTH, <http://www.genome.gov/10002335>, archived at <http://perma.cc/EB7J-MWPS>.

222. See Robert Cook-Deegan et al, *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets*, EUROPEAN JOURNAL OF HUMAN GENETICS 21, 585-588 (2013), available at <http://www.nature.com/ejhg/journal/v21/n6/full/ejhg2012217a.html>.; See also Brinckerhoff, *supra* note 219.

permutation of a disease correlated gene and that patient's personal risk, which would allow a diagnostic laboratory with a more powerful test to leverage their proprietary database into a sale to that particular doctor and patient.²²³ However, one significant problem with this method of maintaining competitive advantage lays in the fact that academic research, which is generally published and made widely available, will likely allow competitors to amass the same knowledge concerning the disease correlation of the targeted gene.

E. Price Point Competition

Finally, price point competition is still a viable method for maintaining competitiveness in the diagnostics marketplace. After all, patients and insurance companies are consumers of diagnostics. It is well established that consumers respond favorably to lower prices.²²⁴ A diagnostics company that is able to provide a robust and accurate test at a competitive price should be able to secure enough market share to recoup their investment.²²⁵

CONCLUSION

Many commentators on both sides predicted the grave consequences of the decision in *Myriad*. The decision in *Myriad* has certainly shaken up the diagnostics market, but the promise of genetics is too great for the industry to die. The genetic diagnostics industry will simply need to develop a new framework by which it attempts to protect investments into genetic research and diagnostics development. The remaining viability of method patents should allow many innovator companies to focus their efforts on creating more accurate, efficient, and robust diagnostics with the security that the methods they create to do so will likely be protected by patent. Furthermore, federal funding into genetic research along with increasing private academic research due to a decrease in anxiety

223.*Id.*

224.*See Law of Demand*, INVESTOPEDIA, <http://www.investopedia.com/terms/l/lawofdemand.asp>, archived at <http://perma.cc/J8RW-PVVE> (explaining the economic principle known as the "Law of Demand").

225.*Id.*

regarding infringement suits may allow for innovator companies to further shift their resources toward the development of diagnostics and away from securing licenses to gene patents and researching the link between genetic polymorphs and disease. Additionally, the adoption of any of several proposed regulatory exclusivity schemes would create a valuable, concrete, and secured incentive for genetic researchers and diagnostic companies to continue using the current exclusivity based model of protecting research and development investment.